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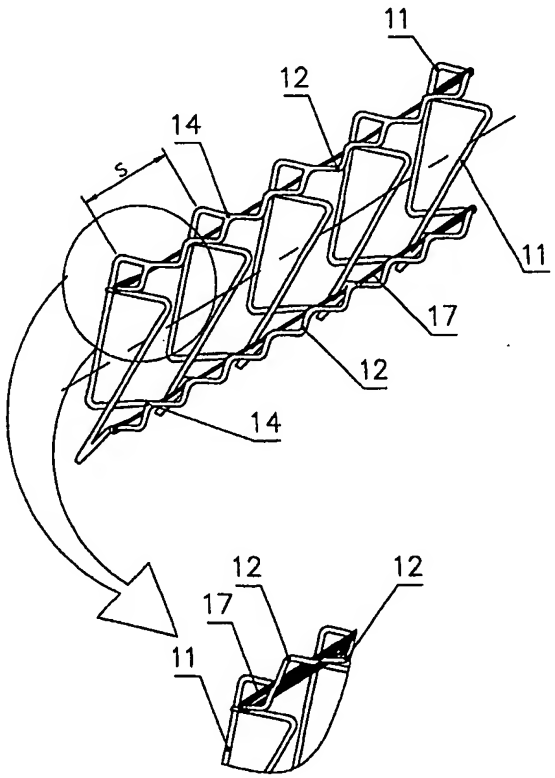
(54) Title: THE BALLOON EXPANDABLE SHEET STENT AND TECHNOLOGY OF ITS MANUFACTURING

(57) Abstract

The Balloon Expandable Sheet Stent is intended for the better support of a diseased vessel wall on the basis of securing the very best thromboresistant properties and raise in the serviceability of a stent in a vessel. The stent (19) comprises a cylindrical surface formed by semi–circular bands (20) oppositely located along the stent longitudinal axis and displaced one against another for a calculated step, and arc–shaped links (12) uniting the said semi–circular bands (20) between themselves on their loose diametrical ends (15) over a generating line of the said stent cylindrical surface. The said stent cylindrical surface is preliminary formed on the surface of a thin sheet metallic blank (13) in a shape of a stencil (10) of calculated geometrical profile constructive elements with the final linear and diametrical sizes of the stent design. In a state of the said stencil (10) one group (11) of the said calculated geometrical profile constructive elements is executed with a possibility of bending and shaping of pockets (16) with clearances for a deployment of bioabsorbable components for local drug delivery, the other group (12) of these constructive elements is executed with a possibility of flanging on both sides from the said stencil longitudinal axis and shaping of a lumen for the deployment of an uninflated balloon (18) of the conducting catheter. The proposed stent design could be manufactured with the application of a simple unwasted technology.



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THE BALLOON EXPANDABLE SHEET STENT and TECHNOLOGY of its MANUFACTURING

Field and Background of the Invention

The present invention relates generally to medical technology, particularly to expandable cardiovascular stents, which are intended for the radical arterial lumen recovery with subsequent restoring of the normal blood flow.

In the present application the term "stent" refers to the device designed to expand the blood vessel and to maintain the achieved size of lumen. Traditionally, stents are delivered to the target area in the cardiovascular system on the inflatable balloon located on the tip of a transluminal catheter. Then, the balloon is inflated leading to the expansion of the stent thereby widening the lumen of the vessel. Other less common systems for stent delivery also exist.

Most of the existent stents made from metals. The examples of common designs described in patents are: US 4.733.665, US 4.969.458, US 5.102.417, US 5.195.994, US 5.513.444, WO 91FR013820. Certain properties of any metallic surface lead to thrombogenicity of the stent once it is implanted within the human cardiovascular system. Therefore, one of the important directions in the stent development is the improvement of the stent thromboresistance because this would reduce the in systemic anticoagulation therapy thereby reducing complication rate after stent implantation. In the present, none of the metallic stents designs have achieved the delicate balance between the desired durability to sufficiently support the vessel wall and flexibility to reduce the thrombogenicity and intimal hyperplasia. Thus, there is a substantial need for anticoagulation and thrombolitic therapy following stent implantation.

Utilization of metal in the stent design leads to further flaws. One of limitations of metallic stent is a presence of more or less rigid kinematic link between constructive elements of radial strength and flexibility. This factor creates additional difficulties during the delivery of the stent to the target area in the coronary artery, especially in distal segments of the vessel. This factor also plays a major role in the shortening of the stent upon stent inflation, which may lead to the suboptimal implantation of the stent, especially in diseased segments of blood vessels, and also this may activate undesirable postprocedural processes, such as thrombosis and restenosis.

The rigidity of a kinematic link between the constructive elements of radial strength and flexibility in already complicated geometrical forms of the stent structure does not allow to use thin metal plates in the stent manufacturing, on the contrary, it requires high inflation pressures upon the deployment of the stent to prevent the stent from collapsing into the vessel lumen. However, ideally, a stent structure should combine the longitudinal flexibility and radial rigidity, which would correspond optimally to the characteristics of pulsating coronary arteries.

Despite the fact the descriptions of most conventional stents claim that these are low profile stents, in fact, all known stents have profiles in the range of 1.3-1.6 mm. This is due to the limitations of the technology of stent manufacturing. All stents are placed on balloons with a minimal diameter of 1.6 mm, which already restricts clinical applications of stents in small vessels. There is no known stent, which parameters would permit it to be used in vessels 2 mm or less.

The additional advantage of a stent structure is an ability to perform an adjunctive

angioplasty after the deployment of the stent. This also permits the better adjusment of the stent to the arterial wall due to the deeper penetration of the stent outer elements into the media and the atherosclerotic plaque.

One of the disadvantages, on the other hand, is the metallic surface of a stent in general, and especially the texture of the surface, which can attract the blood elements and activate the formation of the thrombus, as well as initiate the exaggerated healing process, which through the proliferation of the smooth muscle cells results in restenosis. Therefore, the important part of the stent design is the ability to accommodate various bioabsorbable polymers within itself, which can be loaded with antithrombotic and/or antiproliferative pharmacologic agents with high concentrations. Thus, these agents, delivered locally into the arterial wall, can prevent thrombosis, neointimal proliferation and also avoid unwanted systemic side effects. However, so far the results of clinical experiments with polymer coated stents show frequent occurrence of inflammatory reactions to the polymers by the vessel wall, which limits their clinical applications.

Another important limitation of the stenting is an expensive technology of the stents' manufacturing, which involves the laser technology in almost all known stents, which lowers the cost-effectiveness of the device, and, therefore it's utilization in clinical practice. This technology also leaves the quality of the stents' surface suboptimal, with subsequent higher percentage of thrombus formation on this surface.

In summary, the "ideal" stent should possess the following high quality properties: flexibility, trackability, non-shortness, ultra-low profile, visibility in the X-rays, thromboresistance, biocompatability, reliable expandability, wide range of

available sizes, optional capability of the local drug delivery, and low cost (see, P. Ruygrok and P. Serruys Intracoronary stenting. "Circulation", 1996, 882-890). These features will widen clinical applications of stenting, enable the reduction of unwanted side effects, and ultimately improve the clinical outcome.

The Prior Art

The most effective technical solution for the slotted tube stents, combining both flexibility and radial durability is proposed in the patent application PCT/IL 96/00148 filed on 12.11.1996.

In the above mentioned invention the constructive element, which provides the radial strength of the stent, is constructed in a form of a series of circular bands (2, Fig. 1), disposed over a common longitudinal axis with a number of curvilinear components (3), which play a role of compensators of the diametrical deformation (CDDs). CDD comprises of a least two rods (4), conjugated in the apex (5) by a V-shaped connection. The loose ends of the rods (4) are closed by the undeformable segments (6) of the circular bands (2).

Upon the expansion of the stent (1), resulting from the outward forces from the inflating balloon, CCDs enable the increase of the diameter of each circular bands (2) up to a certain predetermined size where the degree of the diameter increase is proportional to the number of the CDDs. The maximal diameter of the circular band (2) corresponds to the inner diameter of the vessel wall, and the circular band (2) in this position takes shape of almost ideal circle with width of the one CDD rod. The number of circular bands varies from 2 to 40 depending on the length of the stent.

The longitudinal flexibility of the stent is based on the separation of the static and

dynamic functions between the circular bands (2) and the constructive elements of flexibility (7) of the stent, which connect the CDDs. Where the circular band (2) with CDD performs only static function of preventing the vessel wall from collapsing, the constructive element of flexibility (7) of interconnecting zone possesses the significant dynamic function as well, because it needs to reflect the differences in the various segments of the vessel. On another hand, the latter element (7) does not transfer the deformation to the circular bands (2). Therefore, it plays a role of the compensator of the longitudinal deformation (CLD).

CLD (7) comprises of two rods (8), conjugated at the apex (9) by V-shaped 90 degree oriented connection. All the rods (8) have the same length and their loose ends are closed by the undeformable segments (6) of the circular bands (2).

The degree of flexibility of the stent depends on the sum of lengths of all CLD rods. Therefore, the optimal positioning of the CLDs between CDDs during manufacturing becomes very important to achieve the maximum possible number of CLDs on each stent.

Fig. 2 shows that the expansion of the stent only CDDs change their geometrical forms, whereas CLDs, connected to the undeformable segments (6), do not receive the deformation force from the expansion. On another hand, since all junctions (4) of the CDDs have the same size, the stent maintains the cylindrical shape after the expansion.

The discussed invention also describes the effective approach to increase the longitudinal flexibility of a stent to match the changes of the shape of the pulsating vessel. This can be accomplished by producing CLDs from the bioabsorbable polymer material. However, that patent application does not describe any

particular engineering solution to this idea, probably, because the described model is a slotted tube stent, which almost excludes the possibility of incorporating biodegradable materials.

Another limitation of the slotted tube stent design comes from certain short--comings of manufacturing process, which is most of cases is a laser technology. Particularly, this technology limits the accuracy of the length of CDD rods, the radius of the curve in the V-shaped structures, and the optimal position of the CDDs and CLDs in the original shape of the stent. This may potentially lead upon the expansion of the stent in the moving vessel to the deformation of the stent with subsequent activation of the processes of intimal hyperplasia and thrombosis.

Taking into consideration that the discussed model of the stent is the closest one the "ideal" stent among slotted tube stents, this design nevertheless contains some unresolved flaws, which need to addressed to improve the clinical outcome and minimize such unwanted effects of stenting as thrombosis and restenosis.

Therefore, the future "ideal" expandable stent must possess the following characteristics:

1. Maximal radial strength.
2. Correspondence with the shape of the vessel.
3. Compliance to the pulsating vessel.
4. Non-shortning on expansion.
5. Minimum low profile.
6. Accommodation of additional angioplasty.
7. Visibility in X-rays.
8. Capability of local drug delivery.

9. Low manufacturing costs with a high quality easily reproducible manufacturing technology, thus meeting the modern requirements of a cost-effective medical device.

Summary of the Invention

The purpose of the invention is creation of a stent design with a necessary complex of thromboresistant properties including those of minimum low profile before the expansion and non-shortened state upon the expansion of the stent, and provision of a possibility to manufacture devices according to a simple unwasted technology.

This aim is achieved by the fact that the Balloon Expandable Sheet Stent comprises a cylindrical surface formed by a multitude of strutted constructive elements executed in a shape of semi-circular bands oppositely located along a stent longitudinal axis and displaced one against another for a calculated step, and by a multitude of outlined constructive elements executed in a shape of non-strutted links. The said outlined constructive elements unite the said semi-circular bands together on their loose diametrical ends and are located over the generating line of the said stent cylindrical surface.

The essential different sign of the Balloon Expandable Sheet Stent consists in a fact that the said strutted and outlined constructive elements of the said stent cylindrical surface are preliminary formed on the surface of a thin sheet metallic blank in a shape of a stencil of calculated geometrical profile constructive elements with the final linear and diametrical sizes of the stent design.

In the said, preliminary formed, stencil of the calculated geometrical profile constructive elements a prior part of the said sheet metallic blank surface area is

occupied by the said strutted constructive elements that have a possibility, upon the execution of the said stencil, of a free relative spatial positioning along the said stent longitudinal axis.

In a state of the said stencil the outlined constructive elements of the calculated geometrical profile are executed with a possibility of bending and shaping pockets with clearances in the units of their connection with the loose diametrical ends of the strutted constructive elements of the calculated geometrical profile. Upon the expansion of the said stent the said outlined constructive elements do not take the strutted forces from a inflatable balloon, and are only additionally pressed by the said pockets to the generating line of the said stent cylindrical surface, eliminating the said pockets clearances and integrating into the vessel wall.

In a state of the said stencil the strutted constructive elements of the calculated geometrical profile are executed with a possibility of flanging along the both sides from the said stencil longitudinal axis and shaping of a lumen for the deployment of an uninflated balloon in it. Upon the insignificant inflation of the said balloon the said strutted constructive elements of the calculated geometrical profile take up a shape approximating that of a stent non-expanded profile minimum accessible outward diameter. After the expansion of the said stent and the flexible forces from the pulsating vessel the said strutted constructive elements do not take the occurring forces.

The said stent can be supplied with the bioabsorbable components for local drug delivery that are located in the clearances of the said pockets along the said stent longitudinal axis. In this case the shape, volume and geometrical sizes of the said bioabsorbable components are predetermined.

The technological process of stent manufacturing includes the following steps:

- separation of the thin sheet metallic blank with a multiple unwasted quantity of the stent designs with their final linear and diametrical sizes;
- execution of a stencil of strutted and outlined constructive elements of calculated geometrical profile on the surface of the said sheet metallic blank;
- bending of the outlined constructive elements of the calculated geometrical profile and shaping of pockets with clearances in the units of their connection with loose diametrical ends of the strutted constructive elements of the calculated geometrical profile;
- flanging of the said strutted constructive elements of the calculated geometrical profile along the both sides from the stencil longitudinal axis and of shaping a lumen for the deployment of an uninflated balloon in it;
- separation of a ready device;
- conditioning of the said ready device surfaces;
- location in the said pockets clearances along the stent longitudinal axis of the bioabsorbable components for local drug delivery;
- location of the said ready device on the uninflated balloon of a conductive catheter.

The said stent could also be manufactured in an automatic cycle of the said technological operations.

The proposed Balloon Expandable Sheet Stent possesses the following characteristics:

1. The unique transformation of the sheet metallic blank into a stent regular cylindrical surface.
2. Kinematic structure of the stent cylindrical surface excluding the mutual force

influence of the elements of radial strength and flexibility.

3. Minimum outward diameter of the stent non-expanded profile.

4. Constancy of the linear size both in non-expanded and expanded positions.

5. Accommodation of additional angioplasty.

6. Visibility in X-rays.

7. Capability of bioabsorbable components for local drug delivery.

8. Manufacturing clinical samples with a diameter from 2.0 to 5.5 mm.

9. Manufacturing clinical samples with a length from 3.5 to 80 mm.

10. Manufacturing of the devices with a simple unwasted technology.

Thus, the proposed stent design possesses a complex of the necessary thrombo-resistant characteristics including ultra-low profile before the expansion and non-shortened after the expansion of the stent, and secures the possibility of stent manufacturing with a simple unwasted technology.

Brief Description of the Drawings

This invention is herein described with the help of an examples and references to the accompanying drawings, wherein:

Fig. 1 shows the stent-prototype before the expansion.

Fig. 2 shows the stent-prototype after the expansion.

Fig. 3 shows a stencil of strutted and outlined constructive elements of a calculated geometrical profile is executed on the surface of a thin sheet metallic blank, according to the invention.

Fig. 4 shows bend variants of diametrically located outlined constructive elements with formed pockets having clearances, including:

a) the bend of the outlined constructive elements to one side from the stencil

longitudinal axis;

b) the same as in Fig. 4a, but with bioabsorbable components located in the clearances of the pockets;

c) the bend of the outlined constructive elements along the both sides from the stencil longitudinal axis;

d) the bend of the outlined constructive elements along the both sides and situated in a staggered order along the stencil longitudinal axis;

e) the same as in Fig. 4d, but with several bioabsorbable components located in the clearances of the pockets.

Fig. 5 shows a stent the strutted constructive elements of which are flanged on both sides from the stencil longitudinal axis and form a lumen for the location of an uninflated balloon in it, according to the invention.

where S - a calculated step of displacing opposite strutted constructive elements one against another along stent longitudinal axis.

Fig. 6 shows the same as in Fig. 5, but with bioabsorbable components located in the clearances of the pockets.

Fig. 7 shows a stent part with several bioabsorbable components in the clearances of the pockets as shown in Fig. 6.

Fig. 8 shows a stent before the expansion, according to the invention, which is located on the uninflated balloon.

Fig. 9 shows a stent cross-section, according to Fig. 8, after an insignificant inflation of the balloon and a formation of a stent non-expanded profile, minimum accessible outward diameter.

Fig. 10 shows a stent after the expansion, according to the invention,

Fig. 11 shows a stent part, according to Fig. 10, with bioabsorbable components located in the clearances of the pockets.

Fig. 12 shows a state of strutted and outlined constructive elements before the expansion (a,b) and after expansion (c,d) of the stent, according to the invention.

where L - longitudinal size of the outlined constructive elements.

Specific Description

Fig. 3 shows a stencil (10) of strutted (11) and outlined (12) constructive elements of a calculated geometrical profile formed on the surface of a thin sheet metallic blank (13). Whereas the linear and diametrical sizes of the stent design are the final. The strutted constructive elements (11) are executed, for example, in Z - shaped geometrical profiles and occupy a prior part of the said stencil (10). When forming the said stencil (10) the Z - shaped profiles (11) have a possibility of a free relative spatial positioning along the stencil longitudinal axis. This allows to design minimum low profile devices and provides a possibility for implantation of a stent into a distant and most curved parts of diseased vessel. In the proposed stent design a diameter before the expansion is limited only by the presence of the uninflated balloon with a corresponding diameter.

The outlined constructive elements (12) are executed, for example, in a form of non-strutted arc - shaped links, which connect the Z - shaped profiles (11) in units (14) on their loose diametrical ends (15).

The minimum quantity of the Z - shaped profiles (11) and arc - shaped links (12) in the said stencil (10) of the calculated geometrical profile is four of every element. Maximum quantity of such constructive elements is practically unlimited and

is determined by the necessary clinical requirements.

In a state of the said stencil (10) the arc - shaped links (12) of the calculated geometrical profile are executed with a possibility of bending and shaping pockets (16) with clearances for locating some bioabsorbable components for local drug delivery in them. The bend of the arc - shaped links (12) is done in the units (14) of their connection with loose diametrical ends (15) of the Z - shaped profiles (11) along one or both sides in relation to the stencil longitudinal axis. In Fig. 4 are shown bend variants of diametrically placed the arc - shaped links (12) with formed pockets (16) having clearances for locating some bioabsorbable components for local drug delivery. Fig. 4a corresponds to the bend variant of the arc - shaped links (12) with formed the pockets (16) along one side in relation to the stencil longitudinal axis. Fig. 4b corresponds to the bend variant of the arc - shaped links (12) along one side with bioabsorbable components (17) located in the clearances of the pockets (16). Fig. 4c corresponds to the bend variant of the arc - shaped links (12) with formed the pockets (16) along the both sides in relation to the stencil longitudinal axis. Fig. 4d corresponds to the bend variant of the arc - shaped links (12) with formed the pockets (16) and situated in a staggered order in relation to the stencil longitudinal axis. Fig. 4e corresponds to the bend variant of the arc - shaped links (12) with several bioabsorbable components (17) located in the clearances of the pockets (16).

In a state of the said stencil (10) the Z - shaped profiles (11) are executed with a possibility of flanging along the both sides of the stencil longitudinal axis and of displacing one against another for a calculated step S (Fig. 5, 6, 7). With the flanging of the Z - shaped profiles (11) from the stencil longitudinal axis a lumen is

formed, wherein an uninflated balloon (18) of the conducting catheter is located (Fig. 8). Upon the insignificant inflation of the balloon (18) the Z - shaped profiles (11) take up a shape approximating that of a stent non-expanded profile minimum accessible outward diameter (Fig. 10, pos. 19).

With all this the bended arc - shaped links (12) are situated over a generating line of the stent (19) cylindrical surface along the stent longitudinal axis and are compensators of a longitudinal deformation upon the conduction of the stent to the place of the diseased vessel, and also after the expansion of the stent in the vessel upon the pulsating dynamical loads.

Some bioabsorbable components (17), located in the clearances of the pockets (16), are executed, for example, from a polymer thread or film, which can be loaded with high concentration agents for the sustained local drug delivery. The shape, volume and geometrical sizes of bioabsorbable components (17) are predetermined.

On the outward surface of the polymer thread (17) the marks are made (not shown in the Figures), which are visible in X-rays on the stent body upon the implantation.

Figs. 10, 11 show the stent (19), which is expanded in a vessel by the generally accepted balloon expandable stent method. In can be seen that upon the expanding load the Z - shaped profiles (11) take up the form of undeformed strutted semi--circular bands (20) and displace one against another for a calculated step S. The outward diameter of such semi-circular bands (20) corresponds to the maximum vessel inner diameter, and the width of every semi-circular band approaches that of the Z - shaped profile (11). After the attainment of the semi-circular bands (20) of the maximum vessel inner diameter, the angular apices (21) on the surface of the semi-circular bands (20) integrate into a vessel wall, helping the stent (19)

to adjoin the vascular tissue more closely.

As is seen from Figs. 10, 12 upon the expansion of the stent (19) only the Z - shaped profiles (11) deform and change their geometrical sizes. The arc - shaped links (12), attached to the corresponding undeformed loose diametrical ends (15) of the strutted semi-circular bands (20), do not take the forces and deformations from the expanded load. The arc - shaped links (12) are closely pressed by the pockets (16) to the cylindrical surface generating line of the stent (19), eliminating the clearances lumen and integrating into the vessel wall (additional deformation angioplactic of the diseased vascular tissue). Due to the absence of kinematic link between the Z - shaped profiles (11) and the arc - shaped links (12) the stent (19) does not change its length (L) upon the expansion up to the maximum vessel inner diameter (Fig. 12). At the same time, the semi-circular bands (20) do not react to the flexible forces that occur from the pulsating vessel side (after the expansion of the stent). Upon the heart muscle contraction the installed stent does not violate the natural dynamics of the vessel function, the fact that creates favorable conditions for the normal restoration of the traumatic vascular tissue. This should also be effectively assisted by the reglamented medication therapy with bioabsorbable components loaded into the polymer thread.

Upon designing the stencil (10) of the calculated geometrical profile constructive elements there exists a possibility of creation a stent outward surface with cone--like shape. This is done upon the stencil formation by way of regulating the strutted constructive elements geometrical sizes. Besides, due to the possibility of modifying the volume of the calculated step S between the opposite semi-circular bands (20) situated along the stent longitudinal axis stents could be implanted

into the bifurcated coronary artery.

The technology of manufacturing the proposed stent design is a sum total of the developed operations., whose name and sequence of execution are described in the Summary of the Invention.

One of the important advantages of the proposed technological process is a simple unwasted expenditure of metal, the use of the available operations (as, for examples, stamping, Fhoto-Chemical Machining, Electro-Chemical Polishing) for the formation of the stencil of the calculated geometrical profile constructive elements and a simple transformation of the steet stencil into a cylindrical form of a regular stent. As a whole, this brings the proposed technological process to the level of modern industrial production and allows for the creation of comparatively cheap programme-controlled automatic lines.

Thus, in comparison to the prototype and already the known analogues, the proposed stent design possesses the best thromboresistant characteristics, increases the serviceability of the stent in the vessel and can be made according to the simple unwasted technology. Thanks to this new possibilities are opened for obtaining effective results in the treatment of coronary artery and for an essential raise in the volume of stent application in clinical practice.

Industrial Applicability

The proposed balloon expandable sheet stent is a basis for design, production and application of a wide spectrum of cardiovascular samples. The model is recommended for bulk serial and massive production. A preferred mode of the balloon expandable sheet stent production is described above. Still, the construction equivalent elements can be improved without losing the invention advantages, formulated as follows.

What is claimed is:

1. The Balloon Expandable Sheet Stent for insertion in a lumen of a vessel of a living being, comprising:

- cylindrical surface, formed by a multitute of strutted constructive elements, executed in a shape of semi-circular bands oppositely located along the stent longitudinal axis and displaced one against another for a calculated step, and by a multitute of outlined constructive elements, executed in a shape of non-strutted links, the said outlined constructive elements unite the said semi--circular bands together on their loose diametrical ends and are located over a generating line of the said cylindrical surface, whereas the said strutted and outlined constructive elements of the said stent cylindrical surface are preliminary formed on the surface of a thin sheet metallic blank in a shape of a stencil of a calculated geometrical profile constructive elements with the final linear and diametrical sizes of the stent design;

- in the said, preliminary formed, stencil of the calculated geometrical profile constructive elements a prior part of the said sheet metallic blank area is taken by the said strutted constructive elements that have a possibility, upon the execution of the said stencil, of a free relative spatial location along the stencil longitudinal axis;

- in a state of the said stencil the outlined constructive elements of the calculated geometrical profile are executed with a possibility of bending and shaping of pockets with clearances in the units of their connection with loose diametrical ends of the calculated geometrical profile strutted constructive elements, whereas upon the expansion of the said stent the said outlined constructive elements do not take

strutted forces from a inflatable balloon, and are only additionally pressed by the said pockets to the generating line of the said stent cylindrical surface, eliminating the said pockets clearances and integrating into a vessel wall;

- in a state of the said stencil the strutted constructive elements of the calculated geometrical profile are executed with a possibility of flanging along the both sides from the said stencil longitudinal axis and shaping of a lumen for the deployment of a uninflated balloon in it, whereas upon the insignificant inflation of the said balloon the said strutted constructive elements of the calculated geometrical profile take up a shape approximating that of a stent non-expanded profile minimum accessible outward diameter, and after the expansion of the said stent and the flexible forces from the pulsating vessel the said strutted constructive elements do not take the occurring forces.

2. The Balloon Expandable Sheet Stent, wherein a shape, volume and geometrical sizes of bioabsorbable components for local drug delivery are predetermined.

3. The Balloon Expandable Sheet Stent, technological process of manufacturing of which includes the following operations:

- separation of a thin sheet metallic blank with multiple unwasted quantity of the stent designs with their final linear and diametrical sizes;

- execution of a stencil of strutted and outlined constructive elements of a calculated geometrical profile on the surface of the said sheet metallic blank;

- bending of the outlined constructive elements of the calculated geometrical profile and shaping of pockets with clearances in the units of their connection with loose diametrical ends of the strutted constructive elements of the calculated geometrical profile;

- flanging of the strutted constructive elements of the calculated geometrical profile along the both sides from the stencil longitudinal axis and shaping of a lumen for the deployment of an uninflated balloon of the conductive catheter in it;

- separation of a ready device;

- conditioning of the said ready device surfaces;

- location of bioabsorbable components for local drug delivery in the said pockets clearances along the stent longitudinal axis;

- location of the said ready device on the uninflated balloon of the conductive catheter.

4. The Balloon Expandable Sheet Stent as in claim 3, wherein is executed in an automatic cycle of the said technological operations.

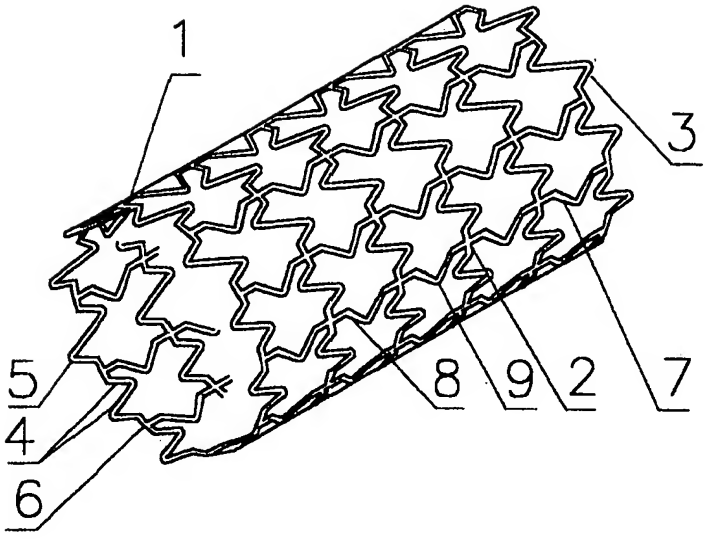

Fig.1

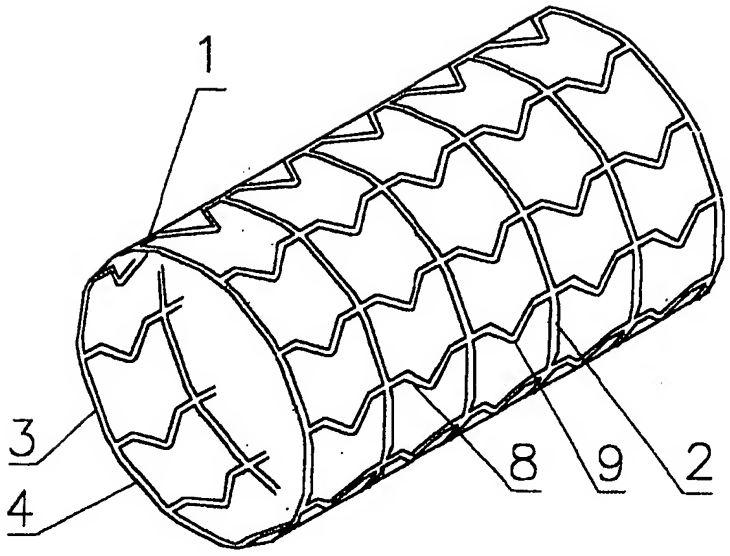

Fig.2

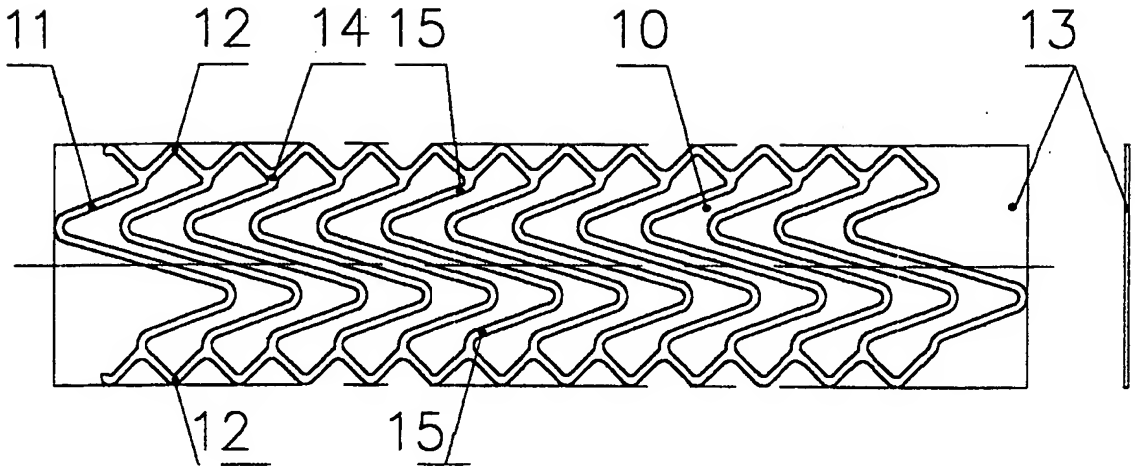

Fig.3

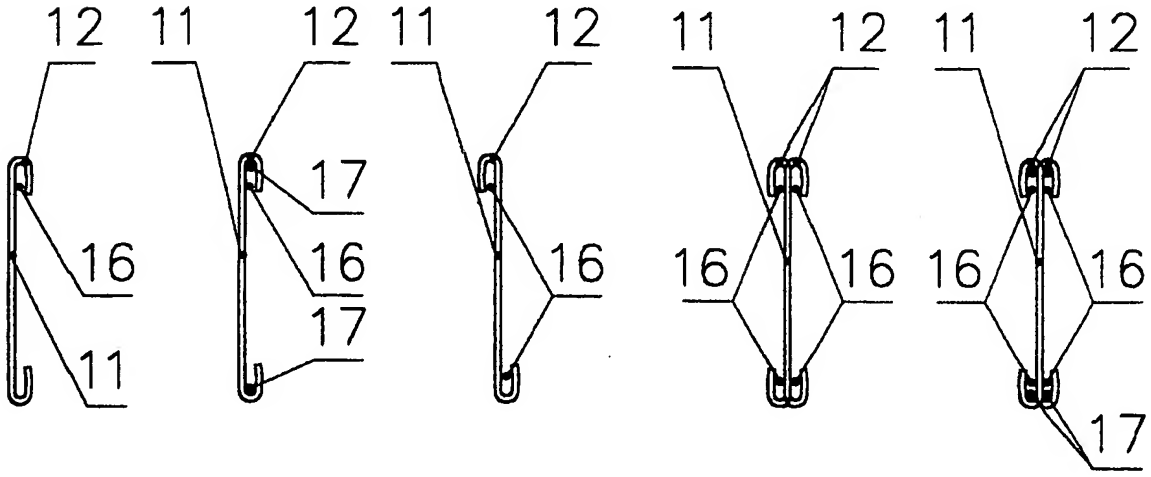

Fig.4a Fig.4b Fig.4c Fig.4d Fig.4e

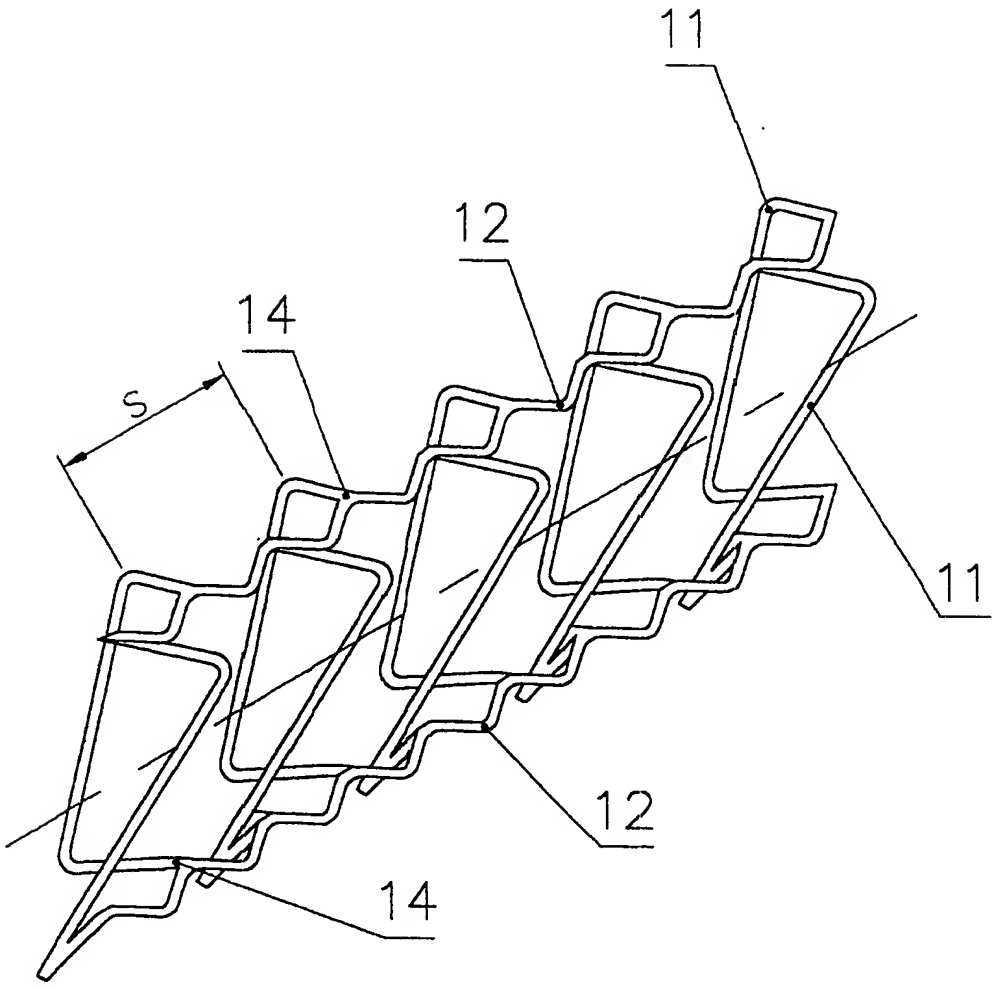

Fig.5

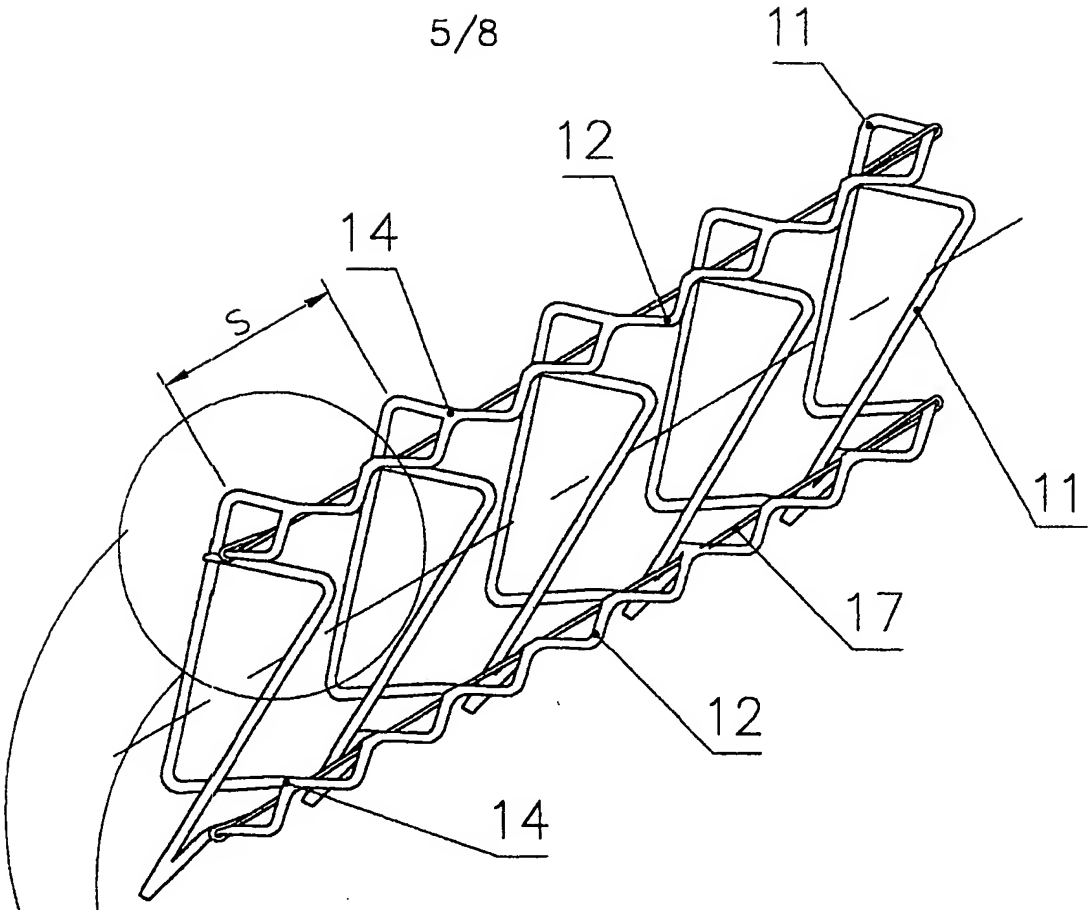

Fig.6

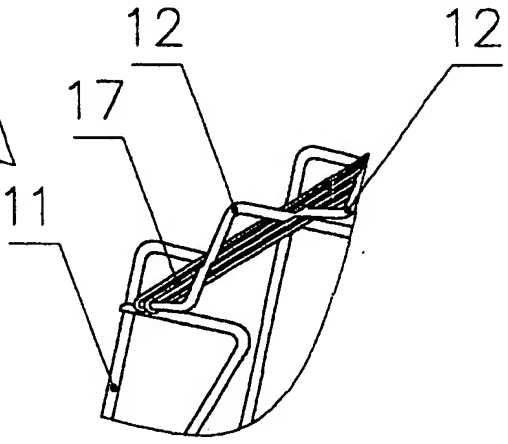

Fig.7

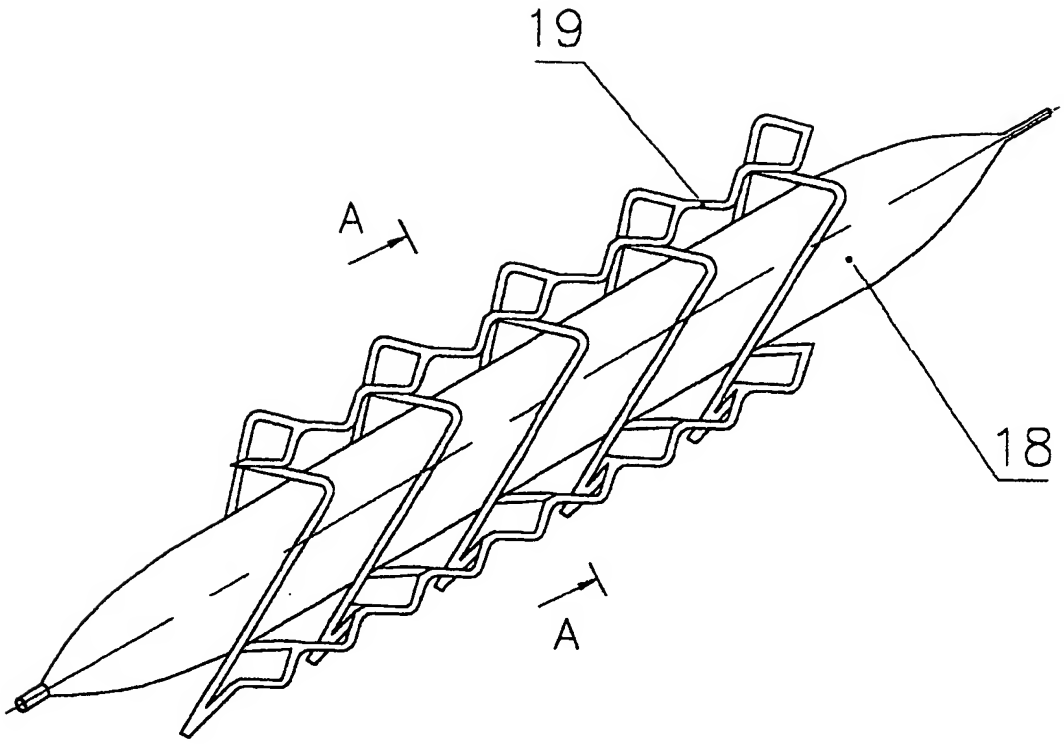

Fig.8

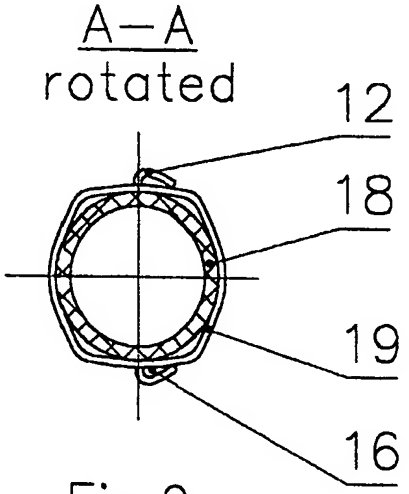

Fig.9

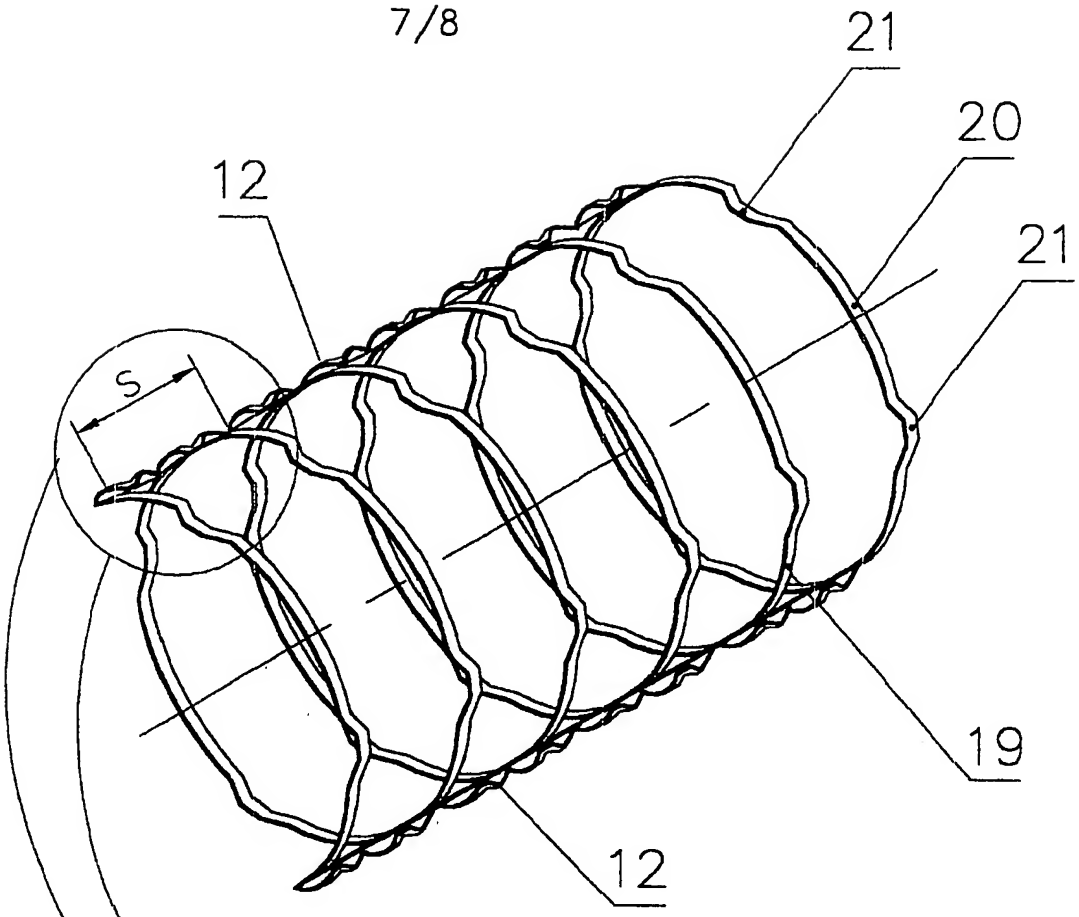

Fig.10

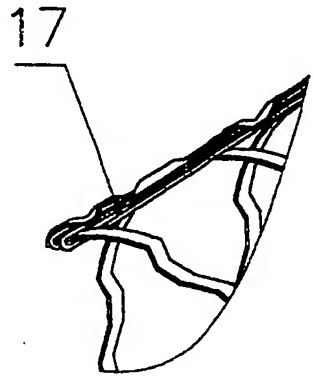

Fig.11

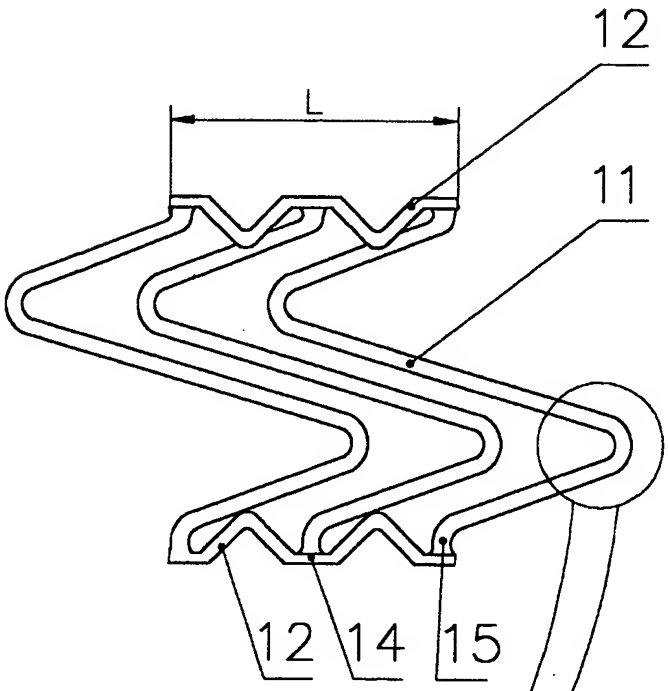

Fig.12a

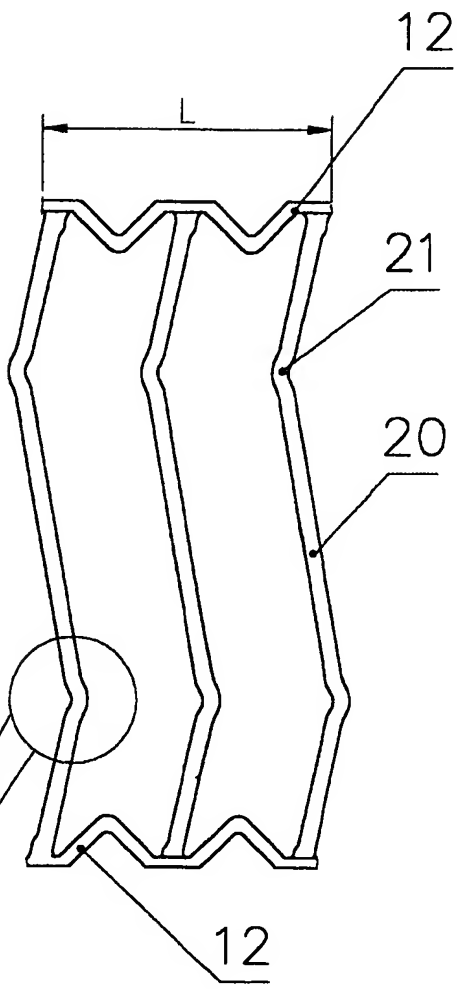

Fig.12c

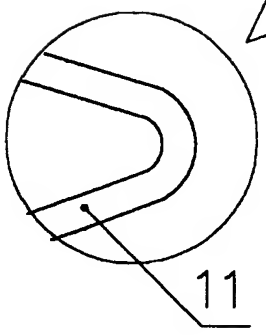

Fig.12b

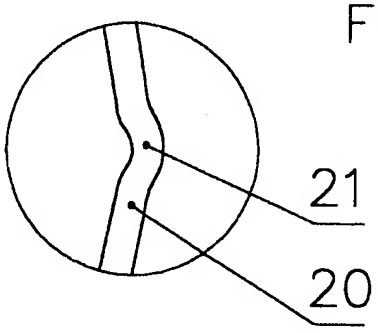

Fig.12d

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00189

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/06
US CL :623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1, 11, 12, 66, 901; 604/104; 606/151-158, 191-200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,578,075 A (DAYTON) 26 November 1996 (26/11/96), col. 5, line 45 through col. 8, line 46; and Figs. 1-14.	1-4
Y	US 5,667,523 A (BYNON et al.) 16 September 1997 (16/09/97), col. 6, line 65 through col. 14, line 67; and Figs. 1-19.	1-4
Y	US 5,681,345 A (EUTENEUER) 28 October 1997 (28/10/97), col. 5, line 61 through col. 8, line 17; and Figs. 1-27.	1-4
Y	US 5,632,771 A (BOATMAN et al.) 27 May 1997 (27/05/97), col. 4, line 48 through col. 9, line 62; and Figs. 1-21, inclusive.	1-4

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 AUGUST 1998	Date of mailing of the international search report 02 SEP 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FRANK CUDDIHY Telephone No. (703) 308-2996

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00189

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,969,896 A (SHORS) 13 November 1990 (12/11/90), col. 3, line 16 through col. 5, line 15; and Figs. 1-7.	1-4
Y	US 5,500,013 A (BUSCEMI et al.) 19 March 1996 (19/03/96), col. 4, line 8 through col. 13, line 51; and Figs.1-8, inclusive.	1-4